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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,889	10/20/2000	Yair Feld	00/20989	7655

7590 09/01/2004  
G. E. EHRLICH (1995) LTD.  
c/o ANTHONY CASTORINA  
SUITE 207  
2001 JEFFERSON DAVIS HIGHWAY  
ARLINGTON, VA 22202

EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/691,889

Applicant(s)

FELD ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23, 24 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 24 and 30-33 is/are rejected.
- 7) ☒ Claim(s) 27-29, 34 and 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed June 1, 2004 has been entered. Claims 23, 27, 30, and 32 have been amended. Claims 36, 38, and 39 have been cancelled.

Accordingly, Claims 23, 24, and 27-35 are pending in the instant application.

The rejection of Claims 23, 24, 31-33, 36, 38, and 39 under 35 U.S.C. 102(b) as being anticipated by Koh et al. (1995) is withdrawn in view of the amendments to the claims, the cancellation of Claims 36, 38, and 39, and the rejection under 35 U.S.C. 103(a), as set forth below.

The rejection of Claim 30 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment to Claim 30.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### ***New Matter***

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claims include new matter.

Claim 32 is directed to the method of Claim 23, wherein the excitable tissue region forms a part of an organ selected from the group consisting of a heart, a pancreas, a kidney, a brain, a smooth muscle,

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a skeletal muscle and a liver. The amendment adds "a smooth muscle" and "a skeletal muscle" to the list of organs. However, Applicants have not pointed to support in the specification as-filed. Specific support is required. The Examiner has reviewed the specification and does not find support for the newly added organs. Although the specification mentions "muscle tissue" in general (p. 22, line 21), it does not specifically mention a smooth muscle or a skeletal muscle. With regard to muscle tissue, the remainder of the specification discusses only cardiac muscle tissue. At pages 7-9 of the specification, only myocardium, nerve cells, and glandular tissue are referred to as being part of the invention. The specification does not contemplate implanting cells into skeletal muscle or smooth muscle. At page 14, paragraph 5, the specification refers to heart, pancreas, kidney, brain, and liver, but notably does not mention smooth muscle or skeletal muscle. Furthermore, the specification does not contemplate modifying the electrophysiological function of a smooth muscle or a skeletal muscle. Absent specific support in the as-filed application, the newly recited terms constitute new matter.

Thus, the amended claims include new matter.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

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to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 24, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koh et al. (1995) and Hoppe et al. (1999).

Koh et al. (1995) disclose successful engraftment of fetal canine cardiomyocytes into the hearts of adult CXMD (canine X-linked muscular dystrophy) dogs. Confocal laser scanning microscopy revealed the presence of connexin43, the major constituent of the cardiac gap junction, at the donor-host cardiomyocyte border. Connexin43 immunoreactivity was apparent at junctional complexes between the donor and host cells (page 2038, column 2, paragraph 1). The reference further contemplates making specific genetic modifications to the donor cells to improve coupling to the host conduction system (page 155

Hoppe et al. (1999) disclose the use of cell fusion to provide premade Kv4.3 ion channels to guinea pig ventricular cardiomyocytes. An expression plasmid encoding rat Kv4.3 is disclosed. The reference further discloses that there is a decrease in  $\text{Ca}^{2+}$ -independent transient outward ( $I_{to1}$ ) current in humans with heart failure and in animal models of heart failure.  $I_{to1}$  is encoded either by Kv4.2 or Kv4.3, or by a combination of the two.

Given the possible association of Kv4.3 and Kv4.2 with heart failure, one of skill in the art would have been motivated to transfect cardiomyocytes with expression constructs encoding either one or both of the ion channels and to subsequently engraft the cardiomyocytes into an animal model of heart failure to study the role of these ion channels in heart failure and determine if their increased expression can restore  $I_{to1}$ , which is decreased in animals with heart failure. In view of the results of Koh et al., one of skill in the art would have expected the donor cardiomyocytes to form gap junctions with host cells.

Therefore, the claimed invention would have been *prima facie* obvious to one of skill in the art at the time of the invention.

*Allowable Subject Matter*

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Claims 27-29, 34, and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet.

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The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER